

Appl. No. 10/510,378  
AMENDMENT  
Docket No. ROS-101

**Amendments to the Drawings**

The attached sheets of drawings includes changes to FIGS. 2-3 and 5. These sheets replace the original sheets.

In FIG. 2, pump 12 is shown.

In FIG. 3, reference number "AD" is deleted and replaced with "1". Sluice mechanism 15 is added.

In FIG. 5, dilatable cuffs C' are shown.

Attachments:            Replacement Sheets

**REMARKS**

Claims 1-15 are pending herein. By this Amendment, Claims 1, 3, 5, 10, and 14-15 are amended. Support for the claim amendments is found in the specification at, *inter alia*, page 15, first full paragraph; page 16, second full paragraph; page 18; and FIGS. 3-4. No new matter is added by this Amendment.

**I. INFORMATION DISCLOSURE STATEMENT**

The Examiner has not considered the two foreign references listed on the Form PTO-1449 submitted with the Information Disclosure Statement filed October 5, 2004. Copies of WO 93/01768 and DE 19904975 were submitted with the Information Disclosure Statement as shown by the last page of the IDS which indicates that "foreign references" were enclosed.

WO 93/01768 is in English. Further, U.S. Patent No. 5,370,685 (the priority document of WO 93/01768) was considered.

An English abstract of DE 199 04 975 was submitted (English abstract of WO 00/45874). Further, the relevance of DE 199 04 975 A1 is given in the specification at page 2 and is relied upon as a statement of the pertinency of these references.

It is believed that these references were submitted in compliance with 37 CFR 1.98(a)(2). However, in the likely event that these references were lost by the U.S. Patent and Trademark Office, copies are attached hereto along with a copy of the Form PTO-1449. Consideration of both references is respectfully requested.

## II. DRAWINGS

Contrary to the Examiner's assertion, the at least one passage (e.g., A1, A2, I, O, C) being provided with a sluice mechanism by which the passage is sealed fluid-tight in an inflated state is shown in FIG. 3. FIG. 3 is amended to shown the sluice mechanism 15 more clearly.

The at least one passage being bound sickle-like by the circumferential edge of the dilation unit and the remaining part by the aortic wall is clearly shown by perfusion catheters C and aorta A in FIG. 3. FIG. 3 also shows at least one passage (e.g., A1, A2) being completely surrounded by dilation unit 2 (see also FIG. 4). FIG. 3 is further amended to replace reference number "AD" with "1".

FIG. 2 is amended to show pump device 12.

FIG. 5 is amended to shown coronary artery perfusion catheters with cuffs C'. This amendment is not new matter. The specification states "the coronary perfusion catheters C are provided at their distal end region with corresponding dilatable cuffs with which the coronary perfusion catheters can be placed and fixed inside the coronary arteries", and therefore supports the amendment to the drawing. See MPEP 608.01(I).

The Examiner asserts that Figure 1 does not clearly show the components of the catheter arrangement. However, Applicants respectfully assert that FIG. 1 is a cross-section of a human heart and schematically shows perfusion catheter 1, dilation units 2,3, guiding catheter 4, and working volume 5 in relation to ascending aorta A, aortic valve AK, left ventricle LK, and left ventricle outflow tract LVOT. Schematic drawings are proper. Further, all of these elements are shown in great detail in the remaining drawings. Consideration of what the drawings would convey to one skilled in the art is essential. One of ordinary skill in the art would easily understand the elements of FIG.1 and their

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relationship with reasonable clarity when read in light of the specification and other drawings.

Applicants respectfully note that sluice elements 11, 11' are shown in FIG. 5. As disclosed in the specification, these externally controlled elements are separate from perfusion catheter 1 (specification at page 17, first full paragraph).

Thus, the drawings comply with 37 C.F.R. 1.83(a). Reconsideration and withdrawal of the objections are respectfully requested.

### III. FORMAL MATTERS

The Examiner objected to the Abstract as being too long and grammatical errors on page 5 of the specification and in Claims 1 and 5.

The Abstract is deleted and a new Abstract is submitted. The specification and Claim 1 are grammatically correct. To clarify the at least one passage, commas are placed around the prepositional phrase “in an inflated state” on page 5 of the specification. Thus, it is clear that the dilation units form - in an inflated state - an at least almost fluid-tight occlusion with the vessel wall or aortic wall. See, for example, FIGS. 2-4. Claim 5 is amended to for clarity to delete the phrases “on the one hand” and “on the other hand”. Reconsideration and withdrawal of the objections are respectfully requested.

Claims 1-13 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This rejection is respectfully traversed.

Claim 1 is amended to clarify that the sluice mechanism seals the at least one passage fluid-tight without the provision of an auxiliary catheter when the dilation unit disposed on the proximal side is in an inflated state (specification at page 16, second paragraph). Claim 3 is amended to clarify that, when said dilation unit is in an inflated state, part of the at least one passage is bound sickle-like by the circumferential edge of

the dilation unit and a remaining part of the at least one passage is bound by the aortic wall. This is clearly shown in FIG. 3.

One of ordinary skill in the art would be able to practice the claimed invention without undue experimentation in view of the specification and drawings. Thus, the requirements of 35 U.S.C. 112, first paragraph, are satisfied. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-13 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is respectfully traversed.

The Examiner argues that it is unclear whether the phrase “in an inflated state” is referring to the sluice mechanism or to the dilation unit (Claim 1). Claim 1 is amended to clarify that the dilation unit is in an inflated state. The Examiner asserts that it is unclear whether the “ring-shaped sluice” of Claim 5 is in addition to the sluice mechanism of Claim 1 or is a different component. Claim 5 is amended to recite a rotatable ring seal (i.e., R of FIG. 3), thereby distinguishing the sluice mechanism of Claim 1. Regarding Claim 10, the Examiner argues that it is unclear what is meant by “opposite channel wall regions”. Claim 10 is amended to recite that the elastic channel has “channel walls”.

The scope of claims would be reasonably ascertainable to one of ordinary skill in the art when read in light of the specification and drawings. Thus, the requirements of 35 U.S.C. 112, second paragraph, are satisfied. Reconsideration and withdrawal of the rejection are respectfully requested.

#### IV. REJECTION UNDER 35 U.S.C. 102(b)

Claims 1-5, 7, and 9-11 were rejected under 35 U.S.C. 102(b) as anticipated by St. Goar et al. (U.S. Patent No. 6,090,096). This rejection is respectfully traversed.

St. Goar et al. discloses a catheter configured to extend into the ascending aorta with a proximal portion of the shaft extending into a left chamber of the heart through the aortic valve and out of the heart through penetration in a wall thereof (Abstract). In the embodiment of the catheter shown in FIGS 8-10, the catheter comprises a flexible shaft 82; lumens 86, 92, 98 extending from respective ports inside the shaft through ventricular balloon 110 to openings 90, 96, and 102 respectively (col. 11, lines 4-18).

St. Goar et al. does not disclose at least a dilation unit disposed on the proximal side with at least one passage (e.g., A1, A2, I, O, C) outside of the at least one perfusion channel through which at least one auxiliary catheter can be introduced for aortic valve ablation in a fluid-tight manner, as recited in Claim 1. See FIG. 3 and FIG. 4 in which it is shown that the at least one passage goes through the dilation unit outside of the perfusion or working channel. St. Goar et al. also does not disclose that the at least one passage projects through said dilation unit disposed on the proximal side and is completely surrounded by said dilation unit, as recited in Claim 4. Thus, St. Goar et al. does not disclose each and every limitation of the claimed device and does not anticipate the claimed device. Reconsideration and withdrawal of the rejection are respectfully requested.

#### V. REJECTIONS UNDER 35 U.S.C. 103(a)

Claim 6 was rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al. in view of Valley et al. (U.S. Patent No. 5,814,016). This rejection is respectfully traversed.

Valley et al. does not overcome the deficiencies of St. Goar et al. Valley et al. discloses devices and methods for temporarily inducing cardioplegic arrest in the heart of a patient and for establishing cardiopulmonary bypass to facilitate procedures on the heart

and its related blood vessels (Abstract). Like St. Goar et al., Valley et al. does not teach or suggest a dilation unit disposed on the proximal side with at least one passage (e.g., A1, A2, I, O, C) outside of the at least one perfusion channel through which at least one auxiliary catheter can be introduced for aortic valve ablation in a fluid-tight manner. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed devices in view of the combined teachings of St. Goar et al. and Valley et al. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 12 was rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al. in view of Kong (U.S. Patent Application Publication 2002/0120234). This rejection is respectfully traversed.

Kong does not overcome the deficiencies of St. Goar et al. Kong discloses a device, system and method for occluding a body lumen such as a blood vessel having an inner wall (Abstract). Like St. Goar et al., Kong does not teach or suggest a dilation unit disposed on the proximal side with at least one passage (e.g., A1, A2, I, O, C) outside of the at least one perfusion channel through which at least one auxiliary catheter can be introduced for aortic valve ablation in a fluid-tight manner. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed devices in view of the combined teachings of St. Goar et al. and Kong. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 13 was rejected under 35 U.S.C. 103(a) as being unpatentable over Goar et al. and Kong in view of Wang et al. (U.S. Patent No. 5,195,969). This rejection is respectfully traversed.

Wang et al. does not overcome the deficiencies of St. Goar et al. and Kong. Wang discloses a medical balloon, a catheter utilizing the balloon, and a mechanism to attach the balloon to the catheter tube (Abstract). Wang et al. does not teach or suggest a

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dilation unit disposed on the proximal side with at least one passage (e.g., A1, A2, I, O, C) outside of the at least one perfusion channel through which at least one auxiliary catheter can be introduced for aortic valve ablation in a fluid-tight manner. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed devices in view of the combined teachings of St. Goar et al., Kong, and Wang et al. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 8 and 14-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al. in view of Boyd et al. (U.S. Patent No. 5,738,652). This rejection is respectfully traversed.

Boyd et al. does not overcome the deficiencies of St. Goar et al. Boyd et al. discloses a retrograde delivery catheter which includes at its distal end a balloon configured to occlude the coronary sinus of a patient's heart (Abstract). Boyd et al. does not teach or suggest a dilation unit disposed on the proximal side with at least one passage (e.g., A1, A2, I, O, C) outside of the at least one perfusion channel through which at least one auxiliary catheter can be introduced for aortic valve ablation in a fluid-tight manner. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed devices in view of the combined teachings of St. Goar et al. and Boyd et al. Reconsideration and withdrawal of the rejection are respectfully requested.

## VI. CONCLUSION

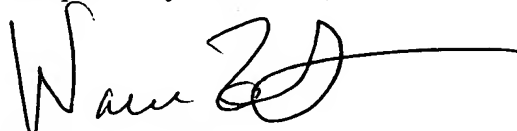
In light of the foregoing remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.



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Any additional fees should be charged to, or any overpayment in fees should be credited to, Deposit Account No. 501032 (Docket #ROS-101).

Respectfully submitted,



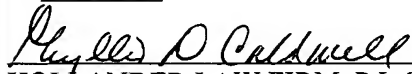
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Attachments:

Replacement Sheets for FIG. 2, FIG. 3, and FIG. 5  
Copy of WO 93/01768  
Copy of DE 19904975 with English Abstract  
Form PTO-1449

CERTIFICATE OF MAILING	
I hereby certify that this correspondence dated <u>9-12-06</u> is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on <u>9-12-06</u> .	
	
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